

## **REMARKS**

### **Claims**

Claims 1–10 are currently under examination with claims 11–25 and 27 withdrawn due to restriction/election and claim 26 cancelled without prejudice or disclaimer.

### **Specification**

The title is in conformance with the length suggested in § 606 of the M.P.E.P.

### **Claim Amendments**

The claims are amended to correct for a typographical error. The amendment is supported by the disclosure contained in the entire specification, as originally filed.

The amended claims further conform to conventional US practice.

The claim amendments do not add new matter.

### **Claim Suggestions**

Applicants thank the Examiner for her suggestions. The claims have been amended accordingly.

### **Rejections under 35 U.S.C. §112, second paragraph**

Claims 1, 3 and 6 stand rejected under 35 U.S.C. §112, second paragraph on the contention that the claim language “use of a microorganism” is allegedly indefinite. Applicants respectfully disagree. It is submitted that Applicants’ specification provides an adequate description of the various reagents and/or reaction conditions that would allow one of ordinary skill in the art to understand the claims readily. The microorganism is “used” to effect the reactions stated.

The objection of Markush language is moot in view of the amendments.

Applicants appreciate the Examiner's careful reading of the claims. The objection of claim 8 is moot in view of amendment of claim 1, to which it is dependent therefrom.

It is courteously submitted that all the pending rejections under 35 U.S.C. §112, second paragraph are moot in view of amendments. Withdrawal of the rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 102(b)**

Claims 6–10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Babcock et al. (US 3,341,557). Applicants respectfully traverse this rejection.

Babcock discloses a process for the hydroxylation of a steroid compound of formula X at the 11-position, comprising using a microbe from the genera *Mucorales*, *Penicillium*, *Aspergillus*, and *Streptomyces* spp. The cited reference is silent regarding the use of *Beauveria* sp., *Curvularia* sp., *Gibberella* sp., *Glomerella* sp., *Gnomonia* sp., *Haplosporella* sp., *Helicostylum* sp., *Nigrospora* sp., and *Syncephalastrum* sp. in the claimed microbiological hydroxylation reactions. See, Applicants' claim 6. Babcock does not disclose all aspects and/or limitations of Applicants' claimed invention. Hence, the cited reference cannot anticipate. Withdrawal of the rejection is therefore respectfully requested.

#### **Rejection under 35 U.S.C. §103(a)**

The rejection of claims 6–10 under 35 U.S.C. §103(a) as allegedly being unpatentable over Babcock et al. (US 3,341,557) in view of Carvajal et al. (US 2,985,563) is respectfully traversed.

The MPEP states that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See, MPEP § 2800.

At page 5, the Office Action contends that in relation to its ability to selectively hydroxylate steroids at the 11-position the microbe *Glomerella* sp. of Carvajal is functionally equivalent to the *Mucorales*, *Penicillium*, *Aspergillus*, and *Streptomyces* spp. taught by Babcock. However, the PTO has not provided any reference materials, for example, patent literature or scientific publications, to support this contention. Moreover, Babcock is silent as to the use of *Glomerella* sp. in hydroxylation of the compounds recited herein. If references were to support the contention that the microbial species were indeed functional equivalents, then Babcock would have utilized Carvajal's teachings and used *Glomerella* sp. to perform the selective hydroxylation reactions or at least stated this was possible.

When it comes to enzymatic reactions, especially in relation to microbiological processes, the art adopts a strict definition of what constitutes "functional equivalency." Usually, genetic homology or similarity and/or complementation of desired activity are used in the characterization of such "functional equivalents." See, for example, the paragraph bridging col. 1 and col. 2 and Figure 6 at page 2188 of the enclosed reference (Sattler et al., *Plant Physiology*, vol. 132, pages: 2184–2195, 2003), which describe "functional equivalency" in bacterial and plant genes encoding  $\alpha$ -tocopherol cyclase (TC). The Office Action has done nothing to support the contention that the microbial species are functional equivalents. Furthermore, neither Babcock nor Carvajal has provided any hint or suggestion that the microbial species could complement, and hence substitute one another. Absent such guidance, a skilled artisan would not be motivated to use *Glomerella* sp. among the vast majority of microbial species to carry out the claimed invention.

The art further recognizes that biological enzymes (proteins) display profound substrate specificity, both at structural as well as the enantiomeric level. The Office Action alleges that Carvajal demonstrates that *Glomerella* is able to selectively hydroxylate "a wide variety of steroids." However, it is submitted that Carvajal's representative steroid substrates, as outlined at col. 2, lines 18–72 of the cited reference, fail to include or suggest the steroid compounds of the instant invention. Applicants therefore respectfully submit that nothing in the cited references would lead a skilled artisan to use the microbial species of Carvajal in the hydroxylation of the compounds claimed herein. The cited references, even at their broadest possible scope, fail to teach or suggest all the aspects and elements of the instant invention. The Office Action has failed to establish *prima facie*

case for obviousness. As such, the pending rejection must be withdrawn.

All rejections must therefore be withdrawn.

In view of the above-mentioned arguments and amendments, it is respectfully submitted that the claims in the application are in condition for allowance. However, if the Examiner has any questions or comments, he is cordially invited to telephone the undersigned at the number below.

No other fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,



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Encl: Reference of Sattler et al.